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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10305]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Revision of a currently approved collection; Title: Medicare Part C and Part D Data Validation (42 C.F.R. §422.516g and §423.514g); Use: The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Part C and Part D sponsoring organizations (Medicare Advantage Organizations [MAOs], Cost Plans, and Medicare Part D sponsors) under the authority described in 42 CFR §422.516(a) and §423.514(a), respectively. Under these reporting requirements, each sponsoring organization must submit Medicare Part C, Medicare Part D, or Medicare Part C and Part D data

(depending on the type of contracts they have in place with CMS).

In order for the reported data to be useful for monitoring and performance measurement, it must be reliable, valid, complete, and comparable among sponsoring organizations. In 2009, CMS developed the data validation program as a mechanism to verify the data reported are accurate, valid, and reliable. To maintain the independence of the validation process, sponsoring organizations do not use their own staff to conduct the data validation. Instead, sponsoring organizations are responsible for hiring external, independent data validation contractors (DVCs) who meet a minimum set of qualifications and credentials.

CMS developed standards and data validation criteria for specific Medicare Part C and Part D reporting requirements that the DVCs use in validating the sponsoring organizations' data.[1] These standards and criteria are described in Appendix 1 "Data Validation Standards." The data validation standards for each measure include standard instructions relating to the types of information that should be reviewed, and measure-specific criteria (MSC) that are aligned with the "Medicare Part C and Part D Reporting Requirement Technical Specifications." Furthermore, the standards and criteria describe how the DVCs should validate the sponsoring organizations' compilations of reported data, taking into account appropriate data exclusions, and verifying calculations, source code, and algorithms. The data validation reviews are conducted at the contract level given that the Medicare Part C and Part D data are generally available at the contract level and the contract is the basis of any legal and accountability issues concerning the rendering of services.

The review is conducted over a three-month period following the final submission of data by the

[1] CMS determines annually which Medicare Part C and Part D measures are included in the data validation program.

sponsoring organizations. In addition to the ”Data Validation Standards” described in Appendix 1, the DVCs employ a set of information collection tools when performing their reviews, which are included in the appendices described below:

Appendix 2: Organizational Assessment Instrument

Appendix 3: Data Extraction and Sampling Instructions

Appendix 4: Instructions for the Findings Data Collection Form

Appendix 5: Findings Data Collection Form (FDCF)

Data collected via “Medicare Part C and Part D Reporting Requirements” is an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare benefits to beneficiaries. CMS uses the data collected through the Medicare data validation program to substantiate the data collected via Medicare Part C and Part D Reporting Requirements. If CMS detects data anomalies, the CMS division with primary responsibility for the applicable reporting requirement assists with determining a resolution. The hour burden on industry is estimated at 179,301 total hours, or 879 hours for one contract within one organization reporting both Part C and Part D measures. The validation would require 378 hours from the sponsoring organization and 501 from the data validation contractors. The estimates are based on the total number of Part C and/or Part D measures, the average number of sponsors, and the average number of contracts by type (Part C, Part D, Part C/D) being validated as well as a level of effort associated with the individual activities associated with the data validation process. Form Number: CMS-10305 (OCN: 0938-1115); Frequency: Reporting – Annually; Affected Public: Private sector – Business or other for-profits; Number of Respondents: 135 Total Annual Responses: 657; Total Annual Hours: 179,301. (For policy

questions regarding this collection contact Terry Lied at 410-786-8973. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at http://www.cms.hhs.gov/PaperworkReductionActof1995, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by **[OFR—insert date 60 days after date of publication in the Federal Register]**:

1. Electronically. You may submit your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

Dated: July 18, 2012

Martique Jones,

Director, Regulations Development Group, Division B

Office of Strategic Operations and Regulatory Affairs.

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